

PCT

INTERNATIONAL SEARCH REPORT

(PCT Article 18 and Rules 43 and 44)

Applicant's or agent's file reference 2973	FOR FURTHER ACTION see Notification of Transmittal of International Search Report (Form PCT/ISA/220) as well as, where applicable, item 5 below.	
International application No. PCT/US 97/ 03347	International filing date(<i>day/month/year</i>) 11/03/1997	(Earliest) Priority Date (<i>day/month/year</i>) 11/03/1996
Applicant AMERICAN BIO MEDICA CORPORATION et al.		

This International Search Report has been prepared by this International Searching Authority and is transmitted to the applicant according to Article 18. A copy is being transmitted to the International Bureau.

This International Search Report consists of a total of 4 sheets.

☒ It is also accompanied by a copy of each prior art document cited in this report.

1. ☐ Certain claims were found unsearchable (see Box I).

2. ☐ Unity of invention is lacking (see Box II).

3. ☐ The international application contains disclosure of a nucleotide and/or amino acid sequence listing and the international search was carried out on the basis of the sequence listing

☐ filed with the international application.

☐ furnished by the applicant separately from the international application,

☐ but not accompanied by a statement to the effect that it did not include matter going beyond the disclosure in the international application as filed.

☐ Transcribed by this Authority

4. With regard to the title, ☒ the text is approved as submitted by the applicant

☐ the text has been established by this Authority to read as follows:

5. With regard to the abstract,

☐ the text is approved as submitted by the applicant

☒ the text has been established, according to Rule 38.2(b), by this Authority as it appears in Box III. The applicant may, within one month from the date of mailing of this International Search Report, submit comments to this Authority.

6. The figure of the drawings to be published with the abstract is:

Figure No. 1 ☒ as suggested by the applicant.

☐ because the applicant failed to suggest a figure.

☐ because this figure better characterizes the invention.

☐ None of the figures.

INTERNATIONAL SEARCH REPORT

Application No
PCT/US 97/03347

A. CLASSIFICATION OF SUBJECT MATTER

IPC 6 A61B10/00 B01L3/00 G01N33/543

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

IPC 6 B01L A61B G01N

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	US 5 119 830 A (DAVIS RICHARD C) 9 June 1992 see the whole document ---	1,3,5
A	US 5 368 583 A (FLEURY RICHARD) 29 November 1994 see column 4, line 59 - column 6, line 23 ---	1,3
A	US 5 352 410 A (HANSEN WARREN D ET AL) 4 October 1994 see column 13, line 24 - column 16, line 34; figures 5-8 ---	1,3
A	WO 95 07659 A (HOFFMANN LA ROCHE) 23 March 1995 see page 6, line 1 - page 9, line 19 --- -/--	1,3,5

☒ Further documents are listed in the continuation of box C.☒ Patent family members are listed in annex.

* Special categories of cited documents :

- *A* document defining the general state of the art which is not considered to be of particular relevance
- *E* earlier document but published on or after the international filing date
- *L* document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)
- *O* document referring to an oral disclosure, use, exhibition or other means
- *P* document published prior to the international filing date but later than the priority date claimed

T later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

X document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

Y document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.

* & * document member of the same patent family

Date of the actual completion of the international search

27 June 1997

Date of mailing of the international search report

23.07.97

Name and mailing address of the ISA

European Patent Office, P.B. 5818 Patentlaan 2
NL - 2280 HV Rijswijk
Tel. (+31-70) 340-2040, Tx. 31 651 epo nl,
Fax (+31-70) 340-3016

Authorized officer

Bindon, C

INTERNATIONAL SEARCH REPORT

Application No
PCT/US 97/03347

C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	EP 0 634 215 A (BOEHRINGER MANNHEIM GMBH) 18 January 1995 see column 2, line 31 - column 6, line 21; figures 3,4 ---	5
A	WO 94 06940 A (ABBOTT LAB) 31 March 1994 see page 3, line 34 - line 37 ---	5
A	US 4 873 193 A (JENSEN RICHARD E ET AL) 10 October 1989 see the whole document ---	1-3
A	FR 2 581 194 A (MATERIEL BIOMEDICAL) 31 October 1986 see abstract; figures -----	1,3

INTERNATIONAL SEARCH REPORT

Information on patent family members

International Application No

PCT/US 97/03347

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
US 5119830 A	09-06-92	AU 1772692 A WO 9217109 A	02-11-92 15-10-92
US 5368583 A	29-11-94	DE 4429885 A GB 2292606 A	07-03-96 28-02-96
US 5352410 A	04-10-94	US 5523055 A	04-06-96
WO 9507659 A	23-03-95	US 5403551 A AU 7695994 A CA 2147498 A CN 1114495 A EP 0668745 A JP 8503556 T NZ 273604 A	04-04-95 03-04-95 23-03-95 03-01-96 30-08-95 16-04-96 28-10-96
EP 0634215 A	18-01-95	DE 4323672 A JP 7077525 A US 5556789 A	19-01-95 20-03-95 17-09-96
WO 9406940 A	31-03-94	AU 4925993 A	12-04-94
US 4873193 A	10-10-89	US 4917867 A US 5186900 A	17-04-90 16-02-93
FR 2581194 A	31-10-86	NONE	

Box III TEXT OF THE ABSTRACT (Continuation of item 5 of the first sheet)

A drug abuse test kit has a transparent cup-like container (1) for retaining a fluid sample to be tested and the open top end (14) of the container (11) is closed by a closure cap (22) seated upon the open end (14). There is a slit (19) in the closure cap (22) to receive a multiple drug test card (25) having a plurality of immunoassay test strips thereon with visual endpoints to indicate presence or absence of a particular drug. The container (11) is provided with a second cover (15) which is solid and unslit to close and seal the container (11) when a sample therein is to be transported.

PCT

REQUEST

The undersigned requests that the present international application be processed according to the Patent Cooperation Treaty.

For receiving Office use only

International Application No.

International Filing Date

Name of receiving Office and "PCT International Application"

Applicant's or agent's file reference
(if desired) (12 characters maximum)

Box No. I TITLE OF INVENTION DEVICE FOR THE COLLECTION, TESTING AND SHIPMENT OF BODY FLUID SAMPLES

Box No. II APPLICANT

Name and address: (Family name followed by given name; for a legal entity, full official designation. The address must include postal code and name of country. The country of the address indicated in this Box is the applicant's State (i.e. country) of residence if no State of residence is indicated below.)

American Bio Medica Corporation
102 Simons Road
Ancramdale, New York 12503
U.S.A.
A corporation of the State of New York

☐ This person is also inventor.

Telephone No.
518-329-4490

Facsimile No.
518-329-4156

Teleprinter No.

State (i.e. country) of nationality:
U.S.A.

State (i.e. country) of residence:
U.S.A.

This person is applicant
for the purposes of:

☐ all designated
States

☒ all designated States except
the United States of America

☐ the United States
of America only

☐ the States indicated in
the Supplemental Box

Box No. III FURTHER APPLICANT(S) AND/OR (FURTHER) INVENTOR(S)

Name and address: (Family name followed by given name; for a legal entity, full official designation. The address must include postal code and name of country. The country of the address indicated in this Box is the applicant's State (i.e. country) of residence if no State of residence is indicated below.)

CIPKOWSKI, Stan
102 Simons Road
Ancramdale, New York 12503
U.S.A.

This person is:

☐ applicant only

☒ applicant and inventor

☐ inventor only (If this check-box
is marked, do not fill in below.)

State (i.e. country) of nationality:
U.S.A.

State (i.e. country) of residence:
U.S.A.

This person is applicant
for the purposes of:

☐ all designated
States

☐ all designated States except
the United States of America

☒ the United States
of America only

☐ the States indicated in
the Supplemental Box

☐ Further applicants and/or (further) inventors are indicated on a continuation sheet.

Box No. IV AGENT OR COMMON REPRESENTATIVE; OR ADDRESS FOR CORRESPONDENCE

The person identified below is hereby/has been appointed to act on behalf
of the applicant(s) before the competent International Authorities as:

☒ agent

☐ common representative

Name and address: (Family name followed by given name; for a legal entity, full official designation. The address must include postal code and name of country.)

JASKIEWICZ, Edmund M.
1730 M Street NW
Suite 400
Washington, D.C. 20036
U.S.A.
U.S. Pat. & TM. Off. Reg.No. 17875

Telephone No.
202-296- 2900

Facsimile No.
202-296-1370

Teleprinter No.

☐ Mark this check-box where no agent or common representative is/has been appointed and the space above is used instead to indicate a special address to which correspondence should be sent.

Box No.V DESIGNATION OF STATES

The following designations are hereby made under Rule 4.9(a) (mark the applicable check-boxes; at least one must be marked):

Regional Patent

- ☒ AP **ARIPO Patent:** KE Kenya, LS Lesotho, MW Malawi, SD Sudan, SZ Swaziland, UG Uganda, and any other State which is a Contracting State of the Harare Protocol and of the PCT
- ☒ EA **Eurasian Patent:** AM Armenia, AZ Azerbaijan, BY Belarus, KG Kyrgyzstan, KZ Kazakhstan, MD Republic of Moldova, RU Russian Federation, TJ Tajikistan, TM Turkmenistan, and any other State which is a Contracting State of the Eurasian Patent Convention and of the PCT
- ☒ EP **European Patent:** AT Austria, BE Belgium, CH and LI Switzerland and Liechtenstein, DE Germany, DK Denmark, ES Spain, FI Finland, FR France, GB United Kingdom, GR Greece, IE Ireland, IT Italy, LU Luxembourg, MC Monaco, NL Netherlands, PT Portugal, SE Sweden, and any other State which is a Contracting State of the European Patent Convention and of the PCT
- ☒ OA **OAPI Patent:** BF Burkina Faso, BJ Benin, CF Central African Republic, CG Congo, CI Côte d'Ivoire, CM Cameroon, GA Gabon, GN Guinea, ML Mali, MR Mauritania, NE Niger, SN Senegal, TD Chad, TG Togo, and any other State which is a member State of OAPI and a Contracting State of the PCT (if other kind of protection or treatment desired, specify on dotted line)

National Patent (if other kind of protection or treatment desired, specify on dotted line):

- | | |
|---|---|
| <input type="checkbox"/> AL Albania | <input type="checkbox"/> LU Luxembourg |
| <input type="checkbox"/> AM Armenia | <input type="checkbox"/> LV Latvia |
| <input checked="" type="checkbox"/> AT Austria | <input type="checkbox"/> MD Republic of Moldova |
| <input checked="" type="checkbox"/> AU Australia | <input type="checkbox"/> MG Madagascar |
| <input type="checkbox"/> AZ Azerbaijan | <input type="checkbox"/> MK The former Yugoslav Republic of Macedonia |
| <input type="checkbox"/> BA Bosnia and Herzegovina | <input type="checkbox"/> MN Mongolia |
| <input type="checkbox"/> BB Barbados | <input type="checkbox"/> MW Malawi |
| <input type="checkbox"/> BG Bulgaria | <input checked="" type="checkbox"/> MX Mexico |
| <input checked="" type="checkbox"/> BR Brazil | <input checked="" type="checkbox"/> NO Norway |
| <input type="checkbox"/> BY Belarus | <input checked="" type="checkbox"/> NZ New Zealand |
| <input checked="" type="checkbox"/> CA Canada | <input checked="" type="checkbox"/> PL Poland |
| <input checked="" type="checkbox"/> CH and LI Switzerland and Liechtenstein | <input type="checkbox"/> PT Portugal |
| <input checked="" type="checkbox"/> CN China | <input type="checkbox"/> RO Romania |
| <input type="checkbox"/> CU Cuba | <input checked="" type="checkbox"/> RU Russian Federation |
| <input checked="" type="checkbox"/> CZ Czech Republic | <input type="checkbox"/> SD Sudan |
| <input checked="" type="checkbox"/> DE Germany | <input type="checkbox"/> SE Sweden |
| <input type="checkbox"/> DK Denmark | <input checked="" type="checkbox"/> SG Singapore |
| <input type="checkbox"/> EE Estonia | <input checked="" type="checkbox"/> SI Slovenia |
| <input type="checkbox"/> ES Spain | <input type="checkbox"/> SK Slovakia |
| <input type="checkbox"/> FI Finland | <input type="checkbox"/> TJ Tajikistan |
| <input checked="" type="checkbox"/> GB United Kingdom | <input type="checkbox"/> TM Turkmenistan |
| <input type="checkbox"/> GE Georgia | <input type="checkbox"/> TR Turkey |
| <input type="checkbox"/> HU Hungary | <input type="checkbox"/> TT Trinidad and Tobago |
| <input checked="" type="checkbox"/> IL Israel | <input type="checkbox"/> UA Ukraine |
| <input type="checkbox"/> IS Iceland | <input type="checkbox"/> UG Uganda |
| <input checked="" type="checkbox"/> JP Japan | <input checked="" type="checkbox"/> US United States of America |
| <input type="checkbox"/> KE Kenya | Continuation-in-part |
| <input type="checkbox"/> KG Kyrgyzstan | <input type="checkbox"/> UZ Uzbekistan |
| <input type="checkbox"/> KP Democratic People's Republic of Korea | <input checked="" type="checkbox"/> VN Viet Nam |
| <input type="checkbox"/> KR Republic of Korea | |
| <input type="checkbox"/> KZ Kazakhstan | |
| <input type="checkbox"/> LC Saint Lucia | |
| <input type="checkbox"/> LK Sri Lanka | |
| <input type="checkbox"/> LR Liberia | |
| <input type="checkbox"/> LS Lesotho | |
| <input type="checkbox"/> LT Lithuania | |

Check-boxes reserved for designating States (for the purposes of a national patent) which have become party to the PCT after issuance of this sheet:

In addition to the designations made above, the applicant also makes under Rule 4.9(b) all designations which would be permitted under the PCT except the designation(s) of _____

The applicant declares that those additional designations are subject to confirmation and that any designation which is not confirmed before the expiration of 15 months from the priority date is to be regarded as withdrawn by the applicant at the expiration of that time limit. (Confirmation of a designation consists of the filing of a notice specifying that designation and the payment of the designation and confirmation fees. Confirmation must reach the receiving Office within the 15-month time limit.)

Supplemental Box*If the Supplemental Box is not used, this sheet need not be included in the request.***Use this box in the following cases:****1. If, in any of the Boxes, the space is insufficient to furnish all the information:***in particular:*

- (i) if more than two persons are involved as applicants and/or inventors and no "continuation sheet" is available;
- (ii) if, in Box No. II or in any of the sub-boxes of Box No. III, the indication "the States indicated in the Supplemental Box" is checked;
- (iii) if, in Box No. II or in any of the sub-boxes of Box No. III, the inventor or the inventor/applicant is not inventor for the purposes of all designated States or for the purposes of the United States of America;
- (iv) if, in addition to the agent(s) indicated in Box No. IV, there are further agents;
- (v) if, in Box No. V, the name of any State (or OAPI) is accompanied by the indication "patent of addition," or "certificate of addition," or if, in Box No. V, the name of the United States of America is accompanied by an indication "Continuation" or "Continuation-in-part";
- (vi) if there are more than three earlier applications whose priority is claimed;

*in such case, write "Continuation of Box No. ..." indicate the number of the Box and furnish the information in the same manner as required according to the captions of the Box in which the space was insufficient;**in such case, write "Continuation of Box No. III" and indicate for each additional person the same type of information as required in Box No. III. The country of the address indicated in this Box is the applicant's State (i.e. country) of residence if no State of residence is indicated below;**in such case, write "Continuation of Box No. II" or "Continuation of Box No. III" or "Continuation of Boxes No. II and No. III" (as the case may be), indicate the name of the applicant(s) involved and, next to (each) such name, the State(s) (and or, where applicable, ARIPO, Eurasian, European or OAPI patent) for the purposes of which the named person is applicant;**in such case, write "Continuation of Box No. II" or "Continuation of Box No. III" or "Continuation of Boxes No. II and No. III" (as the case may be), indicate the name of the inventor(s) and, next to (each) such name, the State(s) (and or, where applicable, ARIPO, Eurasian, European or OAPI patent) for the purposes of which the named person is inventor;**in such case, write "Continuation of Box No. IV" and indicate for each further agent the same type of information as required in Box No. IV;**in such case, write "Continuation of Box No. V" and the name of each State involved (or OAPI), and after the name of each such State (or OAPI), the number of the parent title or parent application and the date of grant of the parent title or filing of the parent application;**in such case, write "Continuation of Box No. VI" and indicate for each additional earlier application the same type of information as required in Box No. VI.***2. If the applicant claims, in respect of any designated Office, the benefits of provisions of the national law concerning non-prejudicial disclosures or exceptions to lack of novelty:***in such case, write "Statement Concerning Non-Prejudicial Disclosures or Exceptions to Lack of Novelty" and furnish that statement below.*

Continuation of Box V

Parent application for U.S.A. designation

U.S.A. 11 March 1996 Application no. 08/613,487

Box No. VI PRIORITY CLAIMFurther priority claims are indicated in the Supplemental Box ☐

The priority of the following earlier application(s) is hereby claimed:

Country (in which, or for which, the application was filed)	Filing Date (day/month/year)	Application No.	Office of filing (only for regional or international application)
item (1) U.S.A.	11 March 1996	08/613,487	
item (2)			
item (3)			

Mark the following check-box if the certified copy of the earlier application is to be issued by the Office which for the purposes of the present international application is the receiving Office (a fee may be required):

☒ The receiving Office is hereby requested to prepare and transmit to the International Bureau a certified copy of the earlier application(s) identified above as item(s):

1

Box No. VII INTERNATIONAL SEARCHING AUTHORITY

Choice of International Searching Authority (ISA) (If two or more International Searching Authorities are competent to carry out the international search, indicate the Authority chosen; the two-letter code may be used): ISA / EPO

Earlier search Fill in where a search (international, international-type or other) by the International Searching Authority has already been carried out or requested and the Authority is now requested to base the international search, to the extent possible, on the results of that earlier search. Identify such search or request either by reference to the relevant application (or the translation thereof) or by reference to the search request:

Country (or regional Office):

Date (day/month/year):

Number:

Box No. VIII CHECK LIST

This international application contains the following number of sheets:

1. request : 4 sheets
 2. description : 15 sheets
 3. claims : 4 sheets
 4. abstract : 1 sheets
 5. drawings : 5 sheets

Total : 29 sheets

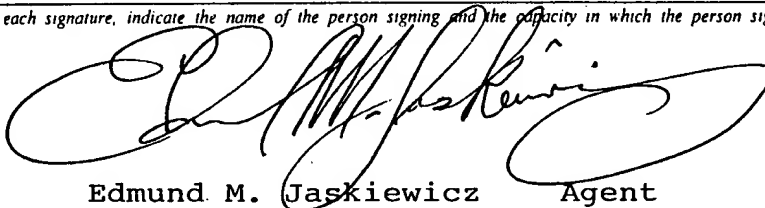
This international application is accompanied by the item(s) marked below:

1. ☒ separate signed power of attorney
 2. ☐ copy of general power of attorney
 3. ☐ statement explaining lack of signature
 4. ☐ priority document(s) identified in Box No. VI as item(s)
 5. ☒ fee calculation sheet
 6. ☐ separate indications concerning deposited microorganisms
 7. ☐ nucleotide and/or amino acid sequence listing (diskette)
 8. ☐ other (specify):

Figure No. 1 of the drawings (if any) should accompany the abstract when it is published.

Box No. IX SIGNATURE OF APPLICANT OR AGENT

Next to each signature, indicate the name of the person signing and the capacity in which the person signs (if such capacity is not obvious from reading the request).



Edmund M. Jaskiewicz Agent

For receiving Office use only

1. Date of actual receipt of the purported international application:	2. Drawings: <input type="checkbox"/> received: <input type="checkbox"/> not received:
3. Corrected date of actual receipt due to later but timely received papers or drawings completing the purported international application:	
4. Date of timely receipt of the required corrections under PCT Article 11(2):	
5. International Searching Authority specified by the applicant: ISA /	6. <input type="checkbox"/> Transmittal of search copy delayed until search fee is paid

For International Bureau use only

Date of receipt of the record copy by the International Bureau:

PCT

FEE CALCULATION SHEET

Annex to the Request

For receiving Office use only

International application No.

Date stamp of the receiving Office

Applicant's or agent's
file reference

2973

Applicant **American Bio Medica Corporation**
102 Simons Road
Ancramdale, New York 12503 U.S.A.

CALCULATION OF PRESCRIBED FEES

1. TRANSMITTAL FEE 230.00 ☐ T

2. SEARCH FEE 1585.00 ☐ S

International search to be carried out by EPO
(If two or more International Searching Authorities are competent in relation to the international application, indicate the name of the Authority which is chosen to carry out the international search.)

3. INTERNATIONAL FEE

Basic Fee

The international application contains 29 sheets.

first 30 sheets 590.00 ☐ b₁

 x = -- ☐ b₂
remaining sheets additional amount

Add amounts entered at b₁ and b₂ and enter total at B 590.00 ☐ B

Designation Fees

The international application contains 24 designations.

11 x 143.00 = 1573.00 ☐ D

number of designation fees amount of designation fee
payable (maximum 11)

Add amounts entered at B and D and enter total at I 2163.00 ☐ I

(Applicants from certain States are entitled to a reduction of 75% of the international fee. Where the applicant is (or all applicants are) so entitled, the total to be entered at I is 25% of the sum of the amounts entered at B and D.)

4. FEE FOR PRIORITY DOCUMENT 15.00 ☐ P

5. TOTAL FEES PAYABLE

Add amounts entered at T, S, I and P, and enter total in the TOTAL box . . .

\$ 3993.00 US

TOTAL

☐ The designation fees are not paid at this time.

MODE OF PAYMENT

☐ authorization to charge
deposit account (see below)

☐ bank draft

☐ coupons

☐ cheque

☒ cash

☐ other (specify:)

☐ postal money order

☐ revenue stamps

DEPOSIT ACCOUNT AUTHORIZATION (this mode of payment may not be available at all receiving Offices)

The RO/ ☐ is hereby authorized to charge the total fees indicated above to my deposit account.

☐ is hereby authorized to charge any deficiency or credit any overpayment in the total fees indicated above to my deposit account.

☐ is hereby authorized to charge the fee for preparation and transmittal of the priority document to the International Bureau of WIPO to my deposit account.

Deposit Account Number

Date (day month year)

Signature

GENERAL POWER OF ATTORNEY

(for several international applications filed under the Patent Cooperation Treaty)

(PCT Rule 90.5)

The undersigned person(s)

(Family name followed by given name; for a legal entity, full official designation. The address must include postal code and name of country.)

American Bio Medica Corporation
102 Simons Road
Ancramdale, New York 12503
U.S.A.

A corporation of the State of New York

hereby appoints (appoint) the following person as:



agent



common representative

Name and address

(Family name followed by given name; for a legal entity, full official designation. The address must include postal code and name of country.)

JASKIEWICZ, Edmund M.
1730 M Street NW
Suite 400
Washington, D.C. 20036
U.S.A.

U.S.A. Patent & Trademark Office
Registration No. 17875

to represent the undersigned before



all the competent International Authorities



the International Searching Authority only



the International Preliminary Examining Authority only

in connection with any and all international applications filed by the undersigned with the following Office

U.S.A.

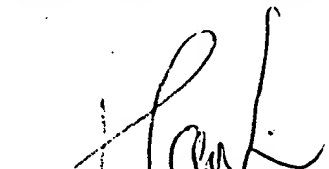
as receiving Office

and to make or receive payments on behalf of the undersigned.

Signatures of the applicant(s) *(where there are several applicants, each of them must sign; next to each signature, indicate the name of the person signing and the capacity in which the person signs, if such capacity is not obvious from reading the request or this power)*

American Bio Medica Corp.

Date:



March 7, 1997

Stan CIPKOWSKI, President